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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,752

04/06/2006

Yunping Luo

TSRI 986.1

2531

2387 7590 10/08/2008

Olson & Cepuritis, LTD.  
20 NORTH WACKER DRIVE  
36TH FLOOR  
CHICAGO, IL 60606

EXAMINER

LI, QIAN JANICE

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

10/08/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



### DETAILED ACTION

The amendment and remarks filed on July 10, 2008 are acknowledged. Claims 2-5, 12-16, 18-22, 24, 25, 31-35, 37, 41, 42, 44, 47-52, 54-57, 60-65 have been cancelled. Claims 1, 6-11, 17, 23, 26-30, 36, 38, 43, 45, 46, 53, 58 have been amended. Claims 1, 6-11, 17, 23, 26-30, 36, 38-40, 43, 45, 46, 53, 58, 59 are pending and under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 6-10, 17, 23, 26-30, 36, 38-40, 43, 45, 46, 53, 58 are rejected under 35 U.S.C. 102(a) as being anticipated by *Luo et al.* (PNAS 2003 Jul;100:8850-5).

*Luo* teaches protection against breast cancer was achieved with a DNA vaccine against murine transcription factor Fos-related antigen 1 (mFra-1), which is overexpressed in aggressively proliferating D2F2 murine breast carcinoma. Growth of primary tumor and dissemination of pulmonary metastases was markedly suppressed by an oral DNA vaccine, which is carried by attenuated *Salmonella typhimurium*

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bacteria, comprising a plasmid encoding murine Fra-1, fused with mutant polyubiquitin, and a plasmid encoding secretory murine IL-18. The life span of 60% of vaccinated mice was tripled and the absence of detectable tumor growth after lethal tumor cell challenge. Accordingly, *Luo* anticipates instant claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 11, 53, 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Luo et al.* (PNAS 2003 Jul;100:8850-5).

The teaching of *Luo* was detailed *supra*. Although *Luo* did not teach to include another plasmid encoding IL-12 in the oral DNA vaccine, *Luo* investigated the immunological mechanisms involved in the anti-tumor immune responses. *Luo* observed markedly increased specific target cell lysis, and a significant release of proinflammatory cytokines IFN-gamma and IL-2, and concluded that this multifunctional DNA vaccine proved effective in protecting against growth and metastases of breast cancer by combining the action of immune effector cells with suppression of tumor angiogenesis. *Luo* also teaches that IL-12 is capable of inducing IFN-g release (see Discussion, column 2, page 8854). Although the treatment was conducted in an animal model, it was a feasibility study for treating human cancer patients.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method taught by *Luo et al*, by including a plasmid expressing IL-12 in the bacteria carrier with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because it may further enhance the anti-tumor immune response. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

### ***Claim Objections***

Claim 1 is objected to because a phrase such as “which bacteria” should be inserted before “comprising” in line 4 in order to clearly set forth the structure of the vaccine.

Claim 26 is objected to because a phrase such as “which bacteria” should be inserted before “comprising” in line 5.

Claim 17 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 6. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

No claim is allowed.

It is noted the new ground(s) of rejection presented in this Office action relies on a publication of which the applicant is a co-author. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. JANICE LI, M.D.** whose telephone number is **571-272-0730**. The examiner can normally be reached on 9 AM -7:00pm, Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Weitach** can be reached on **571-272-0739**. The **fax** numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

*/s/ JANICE LI, M.D./*  
*Primary Examiner, Art Unit 1633*